

PSJ3

Exhibit 239

take him up on his offer to evaluate the dispensing records (I will be happy to do this). This would show that they are trying to exercise due care in confirming the legitimacy of all orders (prior to filling).

In defense of Valley, the new DEA requirement is very complex - and in my opinion, perhaps easier to meet when evaluating a pharmacy that was involved with rogue internet activities. Here we must evaluate the prescriptions themselves to determine whether or not they were issued for a legitimate medical purpose by individual practitioners in the usual course of their professional practices. While the responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, there is clearly a corresponding responsibility resting with the pharmacy. This is very difficult for even DEA to assess - but now they are telling industry to make those judgments - fair or unfair.

We want to help protect Valley and their registration - "they can not afford to make a mistake with one DC." We know that Dan has strongly expressed the desire for Valley to work co-operatively with us on this. He said they are open to anything, including Purdue reducing order quantities. Our primary focus is to help Valley protect its registration and its business in general and especially in distributing our products. We are very appreciative of their work in assuring that our medicine reaches our patients in an appropriate manner and in a timely fashion.

We must be prepared to answer his call if he requests our direct help in the assessment process. This is new territory for a manufacturer and a wholesaler. I will be willing to fly out there and quietly work with them on this assessment, if they ask for our help.

Every now and then we will encounter this type of scenario and we have to decide how we are going to handle it. I understand all sides of this issue. I understand discretion, and I understand how sensitive it is for a distributor to approach a retail customer in trying to conduct its assessments per the DEA mandate.

We know that this is a hot button issue for DEA. This is a very tall order for industry as we will see below:

We asked ourselves **"What can we do to support our own customers - the distributors of our products - and also comply with the DEA mandate.**

We know that the DEA has employed a multi-part strategy to deal with what is referred to as the **"Rogue Internet Pharmacy Problem"** to include seeking and taking Administrative Action against DEA distributor registrants who it claims to have found to be contributing to the illegal distribution of controlled substances over the internet. This Administrative Action includes Orders to Show Cause and Immediate Suspensions of registrations of Distributors of controlled substances.

As you most likely know, it has been learned that DEA is now extending this initiative to include **"Pain Clinics"** and the agency is holding industry to a rigorous standard of Suspicious Order Monitoring.

It has become obvious to us that we should at some point partner with you on certain accounts and help to make decisions about next steps, if any - if that is what you would like.

We have independent information that one of your customers is under investigation or is about to be under investigation by the DEA and/or other law enforcement organizations. We realize that you are probably aware of this and are in the process of assessing the situation. But we want to bring it to your attention - just in case you were not aware of it. Again - we view this as a support function.

I understand discretion, and I understand how sensitive it is for a distributor to approach a retail customer in trying to conduct its assessments per the DEA mandate. I also understand that field investigators and DEA Headquarters personnel (Non-operational types, as I call them ☺) are not always right. I also understand how difficult the issues of "written for a legitimate medical purpose", "in the usual course of professional practice" and "corresponding liability" are to determine. They are very difficult for DEA to assess - and now they are telling industry to make those judgments - fair or unfair.

Our primary focus is to help you protect your registration and your business in general and especially in distributing our products. We are very appreciative of your work in assuring that our medicine reaches our patients in an appropriate manner and in a timely fashion.

Excerpts from DEA/Rannazzisi 2006 Letter:

...Distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes.

.....in addition to reporting all suspicious orders, a distributor has the statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific and industrial channels. Failure to exercise such due diligence could, as circumstances warrant, provide a statutory basis for revocation or suspension of a distributor's registration.

.....given the requirement of 823(e) that a distributor maintain effective controls against diversion, a distributor may not simply rely on the fact that the person placing the order is a DEA registrant and turn a blind eye to the suspicious circumstances. Again, to maintain effective controls against diversion....., the distributor should exercise due care in confirming the legitimacy of all orders prior to filling.

Excerpts from DEA/Rannazzisi 2007 Letter

DEA does not approve or otherwise endorse any specific system for reporting suspicious orders.

The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant.

Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.

Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders.

Lastly, registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 USC 823 and 824, and may result in the revocation of the registrant's DEA Certificate of Registration.

Emerging Interpretation

It is not DEA's intent to negatively impact those pharmacies filling prescriptions for legitimate medical purposes.

Prevent Diversion - onus squarely on the registrant

can a prospective customer be trusted?

exercise due diligence to avoid filling suspicious orders that might be diverted

exercise due care in confirming the legitimacy of all orders prior to filling.

DEA does not approve (any system); DEA does not set limits on what a distributor may sell to a pharmacy.

Must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Distributors need to know to whom they are selling controlled substances, and clearly know their customers' business practices in order to determine whether or not to ship controlled substances. The decision to ship controlled substances to a particular customer rests with the supplier. The supplier must comply with the CSA and implementing regulations.

Know your customers - don't rely on rigid formulas

(Do not) fill these (suspicious) orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels

Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 USC 823 and 824, and may result in the revocation of the registrant's DEA Certificate of Registration.

Purdue recognizes that you have the expertise concerning your retail customers
- therefore we see our role as one of supporting you in your efforts to understand and comply with the stricter emerging interpretations of the regulation.